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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,691	11/17/2003	Wondu Wolde-Mariam	HEBIO.001C1	5375
20995 7590 02/09/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER NGUYEN, BAO THUY L	
			ART UNIT 1641	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			NOTIFICATION DATE	DELIVERY MODE
3 MONTHS			02/09/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/09/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/714,691	WOLDE-MARIAM, WONDU	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 36-83 is/are pending in the application.
- 4a) Of the above claim(s) 50-56, 58, 59, 61, 62 and 79-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-49, 57, 60 and 63-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of claims 36-78 and Species 2 in the reply filed on 04 January 2007 is acknowledged.
2. The following claims read on the elected species and are under consideration: claims 36-49, 57, 60 and 63-78.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 36-49, 57, 60 and 63-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 is confusing with respect to the correlation step. Although the body of the claim requires two different antibodies reactions, the correlation step requires only one reaction to be positive in order for mastitis to be diagnosed. If this is true, this method does not work as claimed. Somatic cells such as leukocytes are normally present in milk samples; it is only when this level is elevated is there a suspicion of mastitis. Having a positive reaction for only the somatic cells alone is not indicative of mastitis.

Claim 39 is vague for the same reason.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 36-49, 57, 60 and 74-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zorah et al., (The Veterinary Record -- IDS) in view of Crist et al (ASC-140 - IDS) and Joyce et al (US 5,168,044).

Zorah discloses the detection of bacterial antigens in milk samples from clinical cases of bovine mastitis. Zorah teaches ELISA for *Staphylococcus aureus*, *Streptococcus agalactiae* and *Streptococcus uberis*, etc by separating whey from the sample. Zorah teaches that using a panel of antibodies to the common mastitis pathogens as taught considerably enhance the diagnosis of clinical mastitis. Furthermore, Zorah discusses the possibility of detecting bacterial antigens in specific quarters of the udder. See *Discussion*, page 210.

Zorah differs from the instant claims in failing to teach the detection of somatic cells.

Crist discloses the characteristic of mastitis as well as its causes and how to determine the cause of the problems. Crist teaches that a symptom of mastitis is an

elevated somatic cell count and that mastitis pathogens are *S. aureus*, *S. agalactiae*, *E. Coli* and *S. uberis*.

Joyce also discloses the detection of somatic cells such as granulocytes and neutrophils using immunoassay to diagnose mastitis.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the detection of somatic cells in the assay panel of Zorah because Crist and Joyce both teach that elevated somatic cells are indicative of mastitis in dairy animals. One skilled in the art would have had a reasonable expectation of success in including the detection of somatic cells along with multiple pathogens suspected of causing mastitis because somatic cells is well known in the art as an indicator of mastitis in dairy animals.

5. Claims 63-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zorah, Crist and Joyce as applied to claim 36 above, and further in view of May et al (WO 88/08534).

Zorah, Crist and Joyce are discussed above. These references differ from the instant invention in failing to teach the use of a lateral flow assay.

May, however, teaches a lateral flow assay device comprising labeled specific binding reagents for an analyte that is freely mobile within a porous carrier when in the moist state, and unlabeled specific binding reagent for the same analyte that is permanently immobilized in a detection zone (page 3). May teaches the use of direct

labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (page 10). May teaches a plurality of detection zones arranged in series on the porous solid phase material through which the aqueous liquid sample can pass progressively. These detection zones can be loaded individually with different specific binding agents to provide a multi-analyte test (page 11). May teaches that two or more discrete test strips, each carrying mobile and immobilized reagents can be arranged in parallel to be used in a simultaneous determination of a plurality of analytes in a single sample (page 12, lines 7-20). May also teaches that their device can be adapted to detection a variety of analytes including hormones, proteins, drugs and infectious agents such as *Streptococcus*, *Neisseris* and *Chlamydia* (page 17, lines 4-14; see also page 18, lines 1-14).


Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by May to detect the multiple pathogens taught by Zorah and Crist because May teaches that their device is suitable for the detection of many different analytes including infectious pathogen. It also would have been obvious to modify the device of May to detect somatic cells such as taught by Joyce because it is well known in the art that somatic cells can be detected using membrane test strip and their detection is advantageous in the diagnosis of mastitis.

*Conclusion*

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641 2/2/07